DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-23-2010 has been entered.

Election/Restrictions

Claims 68-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 2-12-09.

Rejections Withdrawn

Any Objections or Rejections not maintained herein are withdrawn. This action constitutes the complete set of objections/rejections against the claims.

The rejection of claims 49, 54-56, 61-63 and 79 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants argument that protective antigen is not defined as including anthrax peptides and that the specification indicates that anthrax peptides include the full length protective antigen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Upon reconsideration of the art of record, the following rejection(s) are applied.

Claims 49, 54-56, 61-63 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneerson et al (2006/0134143 published June 22, 2006 with priority to 60/476,598 filed on June 3, 2003) in view of Alpar et al , In:MVADS Conference 4th-6ht of June 2003, Dublin, Republic of Ireland.

Schneerson et al teach recombinant PA conjugated to a PGA peptide intended for immunization against anthrax paragraphs [0010-0011] and [0094] of the specification. Schneerson et al teach that the gamma PGA conjugate can be administered to subjects by a variety of mucosal administration routes including oral, rectal, intranasal or intrapulmonary at paragraph [0126]. Schneerson et al teach that the composition includes adjuvants such as MPL among many other suitable adjuvants well known in the art can be included in the compositions at paragraph [0127]. Schneerson et al teach that the conjugate can be dispersed in a base or vehicle and the vehicle can be provided in a variety of forms including fluid, gels, pastes, powders, microspheres and films for direct application to a mucosal surface at paragraph [0128]. Schneerson et al teach that the composition includes kits, packages and multi-container units containing the pharmaceutical compositions optionally multi-dose formulations for use in the prevention or treatment of anthrax. Schneerson et al teach that optional dispensing means can be provides for example, a pulmonary or intranasal spray applicator. Schneerson et al differ by not

teaching combination of two adjuvants (MPL and Chiotosan) with the recombinant PA for mucosal administration in a device.

Alpar et al teach that successful mucosal vaccination is dependent on the development of effective mucosal adjuvants. Alpar et al teach that the adjuvants that have been shown to be mucosally effective are monophosphoryl lipid A (MPL), toxins and immunostimulatory DNA sequences (i.e. the instant agonsits of toll-like receptors) (see paragraph 1). Alpar et al also teach that in previous studies they have shown that chitosan is able to enhance the effects of other adjuvants when administered intranasally.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the recombinant PA conjugated to a PGA peptide to the mucosal adjuvant MPL and the chitosan adjuvant of Alpar et al and formulate the immunogenic composition as a dry powder for use a dispensing means for intranasal administration in single or mulitdose formulations according to Schneerson et al because Schneerson et al teach that the recombinant PA conjugated to a PGA peptide can be so formulated with the MPL and other mucosal adjuvants and dispensed to the mucosal sites such as nasal and Alpar et al teach that chitosan is able to enhance the effects of other adjuvants when administered mucosally to the nose (i.e. intranasal). The dosage, unit or multi-unit formulation packaging along with single or multi-use devices are design choices well established in the art and the choice of unit dosing and multi or single use dispensing devices are well within the skill of the pharmaceutical arts.

Status of the Claims

Claims 68-77 are withdrawn from consideration. Claims 49, 54-56, 61-63 and 79 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Gary Nickol can be reached at 571-272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner